Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0499286	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Frio Regional Hospital	200 South Ih 35, Pearsall, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. A finding of IMMEDIATE JEOPARDY is associated with the following deficiency: 493. 1240 Condition: Pre-Analytic In addition, the following condition level deficiencies were identified: 493. 1217 Condition: Immunohematology 493. 1250 Condition: Analytic 493. 1403 Condition: Laboratory Director; Moderate Complexity 493. 1409 Condition: Technical Consultant 493. 1487 Condition: Testing Personnel; High Complexity NOTE: THE LABORATORY ABATED THE IMMEDIATE JEOPARDY FINDINGS BY PROVIDING A LETTER DATED 10-NOV-22 WHICH STATED THE FACILITY WILL FOLLOW MANUFACTURERS' INSTRUCTIONS FOR SPECIMEN HANDLING AND TESTING REQUIREMENTS.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of laboratory director (or designee) signature on 12 of 20 attestation statements and testing personnel on 1 of 20 attestation statements. The findings include: 1. Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (Chemistry Core Events 2 and 3, Hematology/Coagulation Events 2 and 3, Microbiology Events 2 and 3, Immunology /Immunohematology Events 2 and 3) and 2022 (Chemistry Core Events 1, 2 and 3, Hematology/Coagulation Events 1 and 2, Microbiology Events 1, 2 and 3, Immunology/Immunohematology Events 1 and 2, and Miscellaneous Chemistry

	Events 1 and 2) revealed the laboratory failed to have documentation of the laboratory director (or designee) signature on 12 of 20 attestation statements. They were: 2021 Chemistry Core Event 2 2022 Chemistry Core Event 2 2022 Chemistry Core Event 3 2021 Hematology/Coagulation Event 2 2022 Hematology/Coagulation Event 1 2022 Hematology/Coagulation Event 2 2021 Microbiology Event 2 2022 Microbiology Event 2 2022 Microbiology Event 3 2021 Immunology/Immunohematology Event 2 2022 Immunology/Immunohematology Event 2 2022 Miscellaneous Chemistry Event 2 2. Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (Chemistry Core Events 2 and 3, Hematology/Coagulation Events 2 and 3, Microbiology Events 2 and 3, Immunology/Immunohematology Events 2 and 3) and 2022 (Chemistry Core Events 1, 2 and 3, Hematology /Coagulation Events 1 and 2, Microbiology Events 1, 2 and 3, Immunology /Immunohematology Events 1 and 2, and Miscellaneous Chemistry Events 1 and 2) revealed the laboratory failed to have documentation of testing personnel signature on 1 of 20 attestation statements. It was: 2022 Microbiology Event 1 C. difficile samples 3. The laboratory was asked to provide documentation of the missing signatures. No documentation was provided. 4. An interview with the laboratory manager on 11/07 /2022 at 1535 hours in the conference room - after his review of the records- confirmed the findings.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient transfusion records from August 2022 to October 2022, and staff interview, it was revealed the laboratory failed to follow its policy for having two nurses sign the transfusion record indicating they both positively identified the patient for 2 of 60 transfusions. The findings include: 1. A review of the laboratory's policy titled "Blood Administration Policy and Procedure" (approved by the laboratory director on 01/01/2016) revealed: "7. Two licensed nurses will check blood/blood product for appropriate identification at the patient's bed side. Initial all Patient Identification & Clerical Check STEPS on the form. After verification of all information, the two nurses will sign with the date and time on Blood Transfusion Record and begin transfusion." 2. A review of the laboratory's policy titled "Blood Transfusion and Utilization Review" (approved by the laboratory director on 10/23/2018) revealed: "All units transfused are reviewed for: a. signed doctor's order b. signed consent in medical record c. pre-transfusion criteria d. Two RN signatures before transfusion e. unit started within 30 minutes f. unit transfused within 4 hours g. volume give documented h. all charts not meeting criteria are reviewed by the pathologist i. all data collected is summarized and presented to the pathologist for review monthly. 3. A review of patient transfusion records from August 2022 to October 2022 revealed the form had the following statement: "We certify that before starting the transfusion, we have verified the identification and clerical statements listed above." The form then had spaces for two signatures - Signature of RN handing blood and Signature of RN verifying blood. 4. Further review of the patient transfusion records from August 2022 to October 2022 identified 2 of 60 transfusions where the required nurse's signatures were missing: a) Order 91709 Transfusion date: 09/18/2022 RN hanging blood signature missing RN verifying blood signature missing b) Order 1096 Transfusion date: 10/22/2022 RN

	hanging blood signature missing 5. An interview with the laboratory director on 11/10 /2022 at 1445 hours in the manager's office - after his review of the records- confirmed the findings.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the nursing policies, review of patient transfusion records from August 2022 to November 11, 2022, and staff interview, it was revealed the laboratory failed to ensure nursing policies matched the laboratory's policies for the identification of potential transfusion reactions. The findings include: 1. A review of the laboratory's policy titled "Blood Administration Policy and Procedure" (approved by the laboratory director on 01/01/2016) revealed: "23. Observe patient for any signs of reaction i.e., urticiaria, itching , hives, chills, fever (report to lab any temperature increase over 2 degrees Fahrenheit.), back pain, change in Blood Pressure +/- 20 mm/hg from baseline, dyspenea, chest tightness, increase in heart rate, flushing, hematuria, or nausea. Observe primarily for circulatory overload, febrile reaction, allergic reaction and hemolytic reaction. If any of these symptoms are noted: a) Stop the transfusion immediately..." 2. A review of the nursing policy titled "Blood and Blood Products" revealed the policy failed to identify and define the signs of transfusion reactions and the steps to take if a potential transfusion was suspected. 3. A review of patient transfusion records from August 2022 to November 11, 2022 identified 15 of 68 transfusions where the patients' vital signs met the laboratory's criteria for a potential transfusion, however the transfusion was not stopped and a potential transfusion reaction was not investigated. They were: a) Order 6049 Transfusion date: 11/09/2022 Pre-transfusion Blood Pressure: 148/84 1 Hour Blood Pressure: 174/77 Increase: 26 mm/hg 2 Hour Blood Pressure: 180/89 Increase: 32 mm/hg b) Order 6050 Transfusion date: 11/09/2022 Pre-transfusion Blood Pressure: 147/72 30 minute Blood Pressure: 182/73 Increase: 35 mm/hg 1 Hour Blood Pressure: 174/75 Increase: 27 mm/hg 3 Hour Blood Pressure: 171/80 Increase: 24 mm/hg c) Order 2972 Transfusion date: 10/29/2022 Pre-transfusion Blood Pressure: 78/26 15 minute Blood Pressure: 132/36 Increase: 54 mm/hg 30 minute Blood Pressure: 128/34 Increase: 50 mm/hg 1 Hour Blood Pressure: 119/36 Increase: 41 mm/hg d) Order 1663 Transfusion date: 10/24/2022 Pre-transfusion Blood Pressure: 132/100 1 Hour Blood Pressure: 98/80 Decrease: 34 mm/hg 2 Hour Blood Pressure: 106/58 Decrease: 26 mm/hg 3 Hour Blood Pressure: 88/52 Decrease: 44 mm /hg e) Order 1664 Transfusion date: 10/24/2022 Pre-transfusion Blood Pressure: 154 /88 15 minute Blood Pressure: 117/82 Decrease: 37 mm/hg 30 minute Blood Pressure: 115/60 Decrease: 39 mm/hg 2 Hour Blood Pressure: 133/82 Decrease: 21 mm/hg f) Order 533 Transfusion date: 10/20/22 Pre-transfusion Blood Pressure: 91/57 15 minute Blood Pressure: 120/85 Increase: 29 mm/hg 30 minute Blood Pressure: 130/74 Increase: 39 mm/hg 1 Hour Blood Pressure: 159/99 Increase: 68 mm/hg 2 Hour Blood Pressure: 153/99 Increase: 62 mm/hg g) Order 99483 Transfusion date: 10/17/2022 Pre-transfusion Blood Pressure: 149/54 1 Hour Blood Pressure: 175/65 Increase: 26 mm/hg 2 Hour Blood Pressure: 124/68 Decrease: 25 mm/hg 3 Hour Blood Pressure: 125/72 Decrease: 24 mm/hg h) Order 96637 Transfusion date: 10/07/2022 Pre-

	transfusion Blood Pressure: 89/58 30 minute Blood Pressure: 117/77 Increase: 28 mm /hg i) Order 91406 Transfusion date: 09/16/2022 Pre-transfusion Blood Pressure: 90 /41 15 minute Blood Pressure: 114/66 Increase: 24 mm/hg 30 minute Blood Pressure: 118/61 Increase: 28 mm/hg 1 Hour Blood Pressure: 118/63 Increase: 28 mm/hg 2 Hour Blood Pressure: 117/60 Increase: 27 mm/hg 3 Hour Blood Pressure: 117/64 Increase: 27 mm/hg j) Order 89582 Transfusion date: 09/09/22 Pre-transfusion Blood Pressure: 115/40 1 Hour Blood Pressure: 85/36 Decrease: 30 mm/hg k) Order 87262 Transfusion date: 08/30/2022 Pre-transfusion Blood Pressure: 111/53 30 minute Blood Pressure: 135/58 Increase: 24 mm/hg 1 Hour Blood Pressure: 144/55 Increase: 33 mm/hg 2 Hour Blood Pressure: 145/55 Increase: 34 mm/hg 3 Hour Blood Pressure: 144/73 Increase: 33 mm/hg l) Order 84101 Transfusion date: 08/19/2022 Pre-transfusion Blood Pressure: 109/63 15 minute Blood Pressure: 136/70 Increase: 27 mm /hg 2 Hour Blood Pressure: 156/79 Increase: 47 mm/hg 3 Hour Blood Pressure: 155 /79 Increase: 46 mm/hg m) Order 84102 Transfusion date: 08/19/2022 Pre-transfusion Blood Pressure: 149/76 3 Hour Blood Pressure: 169/83 Increase: 20 mm/hg n) Order 81139 Transfusion date: 08/09/2022 Pre-transfusion Blood Pressure: 131/53 30 minute Blood Pressure: 100/49 Decrease: 31 mm/hg 1 Hour Blood Pressure: 103/45 Decrease: 28 mm/hg 2 Hour Blood Pressure: 82/43 Increase: 49 mm/hg o) Order 80527 Transfusion date: 08/08/2022 Pre-transfusion Blood Pressure: 132/62 2 Hour Blood Pressure: 112/61 Decrease: 20 mm/hg 4. The laboratory was asked to provide documentation the potential transfusion reactions being investigated. No documentation was provided. 5. An interview with the laboratory director on 11/10 /2022 at 1445 hours in the manager's office - after his review of the records- confirmed the findings.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's policies, review of patient transfusion records and staff interview, it was revealed the laboratory failed to meet the requirements for the specialty of Immunohematology. The findings include: 1. The laboratory failed to have documentation of performing 2 of 8 alarm checks as required by its policy (refer to D5555). 2. The laboratory failed to have documentation of reviewing transfusion records to ensure potential transfusion reactions were identified (refer to D5559).
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of the review of 4 of 20 proficiency results. The findings include: 1. Based on review of the laboratory's American Proficiency Institute's

	proficiency testing records from 2021 (Chemistry Core Events 2 and 3, Hematology /Coagulation Events 2 and 3, Microbiology Events 2 and 3, Immunology /Immunohematology Events 2 and 3) and 2022 (Chemistry Core Events 1, 2 and 3, Hematology/Coagulation Events 1 and 2, Microbiology Events 1, 2 and 3, Immunology/Immunohematology Events 1 and 2, and Miscellaneous Chemistry Events 1 and 2) revealed the laboratory failed to have documentation of the review of 4 of 20 results. They were: 2022 Microbiology Event 1 2022 Microbiology Event 2 2021 Immunology/Immunohematology Event 3 2022 Immunology /Immunohematology Event 2 2. The laboratory was asked to provide documentation of the identified proficiency results being reviewed. No documentation was provided. 3. An interview with the laboratory manager on 11/07/2022 at 1535 hours in the conference room - after his review of the records- confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's hematology /coagulation proficiency results from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency test results returned as 'not graded' by the proficiency testing agency for 1 of 4 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's hematology/coagulation proficiency results from 2021 (events 2 and 3) and 2022 (events 1 and 2) revealed the laboratory failed to have documentation of evaluating results returned as 'not graded' on 1 of 4 events. It was: 2022 Event 2 Vaginal Wet Prep - Sample VA02 Blood Cell ID - Sample ECI -6 Sample ECI - 7 Sample ECI - 8 Sample ECI - 9 Sample ECI - 10 2. The laboratory was asked to provide documentation of evaluating the identified results returned as 'not graded'. No documentation was provided. 3. An interview with the laboratory manager on 11/07 /2022 at 1535 hours in the conference room - after his review of the records- confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of the patient test records, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to monitor and correct problems in pre-analytic systems. The finding include: 1. The laboratory failed to identify patient samples for lactic acid testing exceeded the

	manufacturer's required time from collection to testing (refer to D5311 A). 2. The laboratory failed to identify patient samples for partial thromoplastin time testing exceed the manufacturer's required time from collection to testing (refer to D5311 B). 3. The laboratory plan failed to identify patients for Total Prostate-specific Antigen testing did not meet the minimum age requirement as required by the manufacturer (refer to D5311 C). 4. The laboratory's quality assurance plan failed to monitor and correct problems (refer to D5391).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions Alere Epoc Blood Analysis System, review of the manufacturer's instructions for the HemosIL SynthASil, review of the manufacturer's instructions for the Siemens Dimension Total Prostate Specific Antigen assay, review of patient test records from November 2021 to November 2022, and staff interview, it was revealed the laboratory failed to: A) ensure Lactic Assay testing was performed within 5 minutes of collection, B) ensure Partial Thromboplastin Time (PTT) testing was performed within 4 hours of collection, and C) ensure only samples from patients over the age of 50 were tested for TPSA. The findings include: A) Lactic Acid 1. A review of the manufacturer's instructions for the EPOC Blood Analysis System (51008148 Rev. 04) under the section titled "Sample Collection Details" revealed that for lactic acids samples collected in syringes, lithium heparin evacuated tubes, and capillary tubes, the test had to be performed within 5 minutes to avoid the effects of glycolysis. 2. A review of lactate samples tested on the EPOC Blood Analysis System from August 2022 to October 2022 identified 10 of 283 samples where the time from collection to receipt exceeded 5 minutes, and thus testing could not have occurred within the required timeframe. They were: a) Order 82358 collected: 8/13/2022 0848 hours received: 8/13/2022 0857 hours elapsed time: 9 minutes b) Order 82685 collected: 8/14/2022 1636 hours received: 8/14/2022 1647 hours elapsed time: 11 minutes c) Order 84651 collected: 8/21/2022 1050 hours received: 8/21/2022 1100 hours elapsed time: 10 minutes d) Order 88277 collected: 9 /04/2022 0912 hours received: 9/04/2022 0929 hours elapsed time: 17 minutes e) Order 92418 collected: 9/20/2022 1427 hours received: 9/20/2022 1435 hours elapsed time: 12 minutes f) Order 94623 collected: 9/29/2022 0755 hours received: 9/29/2022 0857 hours elapsed time: 62 minutes g) Order 99202 collected: 10/16/2022 0806 hours received: 10/16/2022 0813 hours elapsed time: 7 minutes h) Order 99944 collected: 10/18/2022 1810 hours received: 10/18/2022 1817 hours elapsed time: 7 minutes i) Order 1027 collected: 10/22/2022 0920 hours received: 10/22/2022 0930 hours elapsed time: 10 minutes j) Order 2958 collected: 10/29/2022 1000 hours received: 10/29/2022 1014 hours elapsed time: 14 minutes 3. An interview with the laboratory manager on 11/08/2022 at 1535 hours in the laboratory - after her review of the records- confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/01-02/2021 B) Partial Thromboplastin Time (PTT) testing 1. A review of the manufacturer's instructions for the HemosIL

	SynthASil reagent (revision 06/2017) under the section titled "Specimen collection and preparation" revealed: "Nine parts of freshly drawn venous blood are collected one part 3.2% trisodium citrate. Refer to CLSI (formerly NCCLS) Document H21-A5 for further instructions on specimen collection, handling and storage." 2. A review of CLSI document H21-A5 revealed: "Specimens for routine APTT assays from nonheparanized patients can be maintained uncentrifuged or centrifuged, with plasma remaining on top of cells, in an unopened tube kept at room temperature for up to four hours from time of collection." 3. A review of patient test records from July 2022 to October 2022 identified 5 of 175 samples where the time from collection to testing exceeded four hours. They were: a) Order 73890 collected: 7/15/2022 1445 hours tested: 7/15/2022 1954 hours elapsed time: 5 hours 9 minutes b) Order 74007 collected: 7/16/2022 0958 hours tested: 7/16/2022 1421 hours elapsed time: 6 hours 23 minutes c) Order 81402 collected: 8/10/2022 1110 hours tested: 8/10/2022 1604 hours elapsed time: 4 hours 54 minutes d) Order 88004 collected: 9/02/2022 1348 tested: 9/02/2022 1900 elapsed time: 5 hours 12 minutes e) Order 1869 collected: 10 /25/2022 1330 hours tested: 10/25/2022 2016 hours elapsed time: 6 hours 46 hours 4. An interview with the laboratory manager on 10/09/2022 at 1545 hours in the laboratory - after his review of the records- confirmed the findings. C) Total Prostate-specific Antigen 1. A review of the manufacturer's instructions for the Siemens Dimension TPSA (total prostate-specific antigen) reagent cartridge (issue date 2019-07-29) under the section titled "Intended Use" revealed: "The TPSA method for the Dimension clinical chemistry system with the heterogeneous immunoassay module is an in vitro diagnostic test intended to quantitatively measure total prostate specific antigen (PSA) in human serum and plasma: as an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older..." 2. A review of patient test records from November 2021 to November 2022 (as of the day of the survey) identified 5 of 98 patients who were under the age of 50 and whose samples were tested utilizing the Dimension TPSA test. They were: a) medical number: 337502 tested: 04/15/2022 age: 41 years b) medical number: 337541 tested: 04/16/2022 age: 44 years c) medical number: 341042 tested: 06/15/2022 age: 43 years d) medical number: tested: age: e) medical number: tested: age: 3. An interview with laboratory manager on 11/08/2022 at 1630 hours in his office - after his review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/02/2021.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of the patient test records, review of the laboratory's records, and staff interview, it was revealed the laboratory's quality assurance plan failed to monitor and correct problems in pre-analytic systems. The finding include: 1. The laboratory's quality assurance plan failed to identify patient samples for lactic acid testing exceeded the manufacturer's required time from collection to testing (refer to D5311 A). 2. The laboratory's quality assurance plan failed to identify patient samples for partial thromoplastin time testing exceed the manufacturer's required time from collection to testing (refer to D5311 B). 3. The laboratory's quality assurance plan failed to identify patients for Total Prostate-

	specific Antigen testing did not meet the minimum age requirement as required by the manufacturer (refer to D5311 C).
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of the patient test records, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to monitor and correct problems in analytic systems. The finding include: 1. The laboratory failed to ensure its procedure the patient normal range was followed (refer to D5401). 2. The laboratory failed to ensure verification studies were performed (refer to D5421). 3. The laboratory failed to ensure calibration verifications were performed (refer to D5439). 4. The laboratory failed to ensure quality control values were monitored over time (refer to D5441). 5. The laboratory failed to ensure quality control testing was performed each day of patient testing (refer to D5447). 6. The laboratory failed to ensure its Individualized Quality Control Plan was followed (refer to D5449). 7. The laboratory failed to ensure blood bank alarm checks were performed when required (refer to D5555). 8. The laboratory failed to ensure the review of transfusion records to detect potential transfusion reactions (D5559). 9. The laboratory's failed to ensure its quality assurance plan identified and corrected problems in analytic systems (refer to D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for determining patient normal ranges, review of the laboratory's determination of patient normal means for Prothrombin Time testing done in September 2022, and staff interview, it was revealed the failed to ensure required information was gathered on 20 of 20 study participants. The findings include: 1. A review of the laboratory's Patient Normal Range worksheet revealed the following information was to be collected to ensure patients met the laboratory's criteria to be part of the study: "1. Donors should be generally healthy 2. Donors should not be on any oral anticoagulants (blood thinners) and high dosage of aspirin 3. Donors should not be on hormone replacement or birth control meds and/or estrogen therapy 4. Donors should span the adult range." 2. A review of the laboratory's Patient Normal Range worksheet from September 2022 revealed the laboratory failed to have documentation of the following: a) Donor age for 20 of 20 participants b) Donor

	health for 2 of 20 participants donor 10 and donor 11 c) Donor anticoagulants or high dose aspirin for 2 of 20 participants donor 10 and donor 11 d) Donor hormone/birth control/estrogen for 2 of 20 participants donor 10 and donor 11 3. The laboratory was asked to provide documentation of collecting the required information. No documentation was provided. 4. An interview with the laboratory manager on 11/10 /2022 at 820 hours in his office - after his review of the records- confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's instrumentation, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies on of 3 Alere Epoc Blood Gas analyzers. The findings include: 1. A review of the laboratory's instrumentation on 11/09/2022 at 1345 hours in the laboratory revealed the laboratory had 3 Alere Epoc Blood Gas analyzers in use for patient testing. They were: Epoc #1: serial number 16184521402331 Epoc #2: serial number 14051521402188 Epoc #3: serial number 17279521400783 2. A review of the laboratory's patient test records from April 2022, May 2022 and June 2022 revealed Epoc #2 was placed into service in June 2022 and Epoc #3 was in use from April 27, 2022 to June 15, 2022. The analytes tested were: pH pCO2 pO2 lactic acid 3. The laboratory was asked to provide documentation of performing the required verification studies (accuracy, precision, reportable range) prior to placing Epoc #2 and Epoc #3 into service. No documentation was provided. 4. A review of patient test records from July 2022 to October 2022 revealed the laboratory performed 68 tests on Epoc #2 (see patient alias list #1). 5. A review of patient test records from April 27, 2022 to June 15, 2022 revealed the laboratory performed 60 tests on Epoc #3 (see patient alias list #2). 6. An interview with the laboratory manager on 11/09/2022 at 1415 hours in the laboratory revealed he wasn't sure if verification studies had been performed on Epoc #2. He stated he had no idea Epoc #3 was ever used in the laboratory. This confirmed the findings. II. Based on review of the laboratory's instrumentation, review of the laboratory's verification studies, review of an email from a Siemen's field installation representative, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies for Dimension LOCI Vitamin B12 assay on the Siemens Dimension EXL-LM analyzer (serial number DR252069). The findings include: 1. A review of the laboratory's instrumentation revealed the laboratory placed a new Siemens Dimension EXL-LM (serial number DR252069) into use in May 2022. 2. A review of the laboratory's verification records revealed the laboratory failed to have documentation of verification studies for 1 of 26 analytes. It was: Vitamin B12 3. A review of an email from Siemens' technical support dated May 12, 2022 revealed: "I have attached the installation data for DR252069. Vitamin B12 is having errors hydrating. I am in contact with our technical team to figure out why

	specifically VB12 and no other assay causes Reagent Prep Errors. I took ou the VB12 data until this can be resolved... The instrument is ready for you to use (other than VB12)." 4. The laboratory was asked to provide documentation of performing verification studies (accuracy, precision, reportable range) for the Dimension LOCI Vitamin B12 assay. No documentation was provided. 5. A review of patient test records from May 2022 revealed the laboratory performed Vitamin B12 testing on 45 patients from July 14, 2022 to November 8, 2022 (see patient alias list #3). 6. An interview with the laboratory manager on 11/10/2022 at 1015 hours in the prayer room revealed studies had not been completed for Vitamin B12. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEYS CONDUCTED 01/15/2019 AND 06/01-02/2021
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification records from 2020 to 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing required calibration verifications every six months for the analytes Sodium, Potassium, Chloride and A1C on each of its two Dimension chemistry analyzers. The findings include: 1. A review of the laboratory's calibration verification records from 2020 to 2022 revealed the laboratory failed to perform calibration verification for Sodium, Potassium, Chloride, and A1C at the following time: a) Dimension EXL-LM (serial number: 12251139) June 2021 b) Dimension EXL-200 (serial number: DR271890) June 2021 2. A review of the laboratory's records for the listed assays revealed the laboratory utilized 2 or fewer calibrators and performed quality control testing using 2 levels of quality control material, thus calibration verification was required. 3. The laboratory was asked to provide documentation of performing the required calibration verification in June 2021. No documentation was provided. 4. An interview with the laboratory manager on 11/09/2022 at 1400 hours in the office revealed he was unsure if calibration verification was performed two times in 2021. This confirmed the findings.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from July 2021 to October 2022, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time for testing performed on the Epoc Blood Analysis System analyzers. The findings include: 1. A review of the laboratory's quality control records from July 2021 to October 2022 for blood gas and lactic acid testing performed on the laboratory's three Epoc Blood Analysis System analyzer revealed the laboratory failed to have documentation of monitoring quality control results over time to ensure accuracy and precision. The following analytes were tested on the Epoc systems: pH pCO2 pO2 lactic acid 2. The laboratory was asked to provide documentation of monitoring quality control values over time. No documentation was provided. 3. An interview with the laboratory manager on 11/09 /2022 at 1500 hours in the laboratory revealed the laboratory did to monitor quality control values over time. This confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's quality control records, review of patient test records and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for the Alere Blood Gas System analyzer identified as Epoc #2 and Epoc #3. The findings include: 1. A review of the laboratory's instrumentation on 11 /09/2022 at 1345 hours in the laboratory revealed the laboratory had 3 Alere Epoc Blood Gas analyzers in use for patient testing. They were: Epoc #1: serial number 16184521402331 Epoc #2: serial number 14051521402188 Epoc #3: serial number 17279521400783 2. A review of the laboratory's records from May 2022 and June 2022 revealed Epoc #2 was placed into service in June 2022 and Epoc #3 was used for patient testing from April 27, 2022 to May 15, 2022. The analytes tested were: pH pCO2 pO2 lactic acid 3. Further review of the laboratory's records revealed the

	laboratory had documentation of performing an Individualized Quality Control Plan (IQCP) for Epoc #1. The laboratory was asked to provide documentation of developing an Individualized Quality Control Plan for Epoc #2 and Epoc #3 to support the modification of the frequency of quality control testing. No documentation was provided. 4. A review of the quality control records from May 2022 to October 2022 revealed quality control testing was performed on the following days: a) Epoc #2 July 4, 2022 July 13, 2022 July 15, 2022 July 22, 2022 July 27, 2022 August 4, 2022 August 10, 2022 August 18, 2022 August 26, 2022 September 07, 2022 September 12, 2022 September 23, 2022 October 3, 2022 October 14, 2022 October 21, 2022 October 27, 2022 b) Epoc #3 May 13, 2022 May 19, 2022 4. A review of patient test records from May 2022 to October 2022 identified the following patient samples tested on days without documentation of quality control testing being performed: a) Epoc #2 July 17, 2022 Patient ID: 74223 July 18, 2022 Patient ID: 342875 (1st test) Patient ID: 342875 (2nd test) Patient ID: 342875 (3rd test) July 26, 2022 Patient ID: 343406 July 30, 2022 Patient ID: 77706 August 6, 2022 Patient ID: 344099 August 9, 2022 Patient ID: 34428 August 15, 2022 Patient ID: 344515 August 27, 2022 Patient ID: 345371 Patient ID: 345320 Patient ID: 344942 August 28, 2022 Patient ID: 345364 Patient ID: 344942 September 20, 2022 Patient ID: 346766 September 22, 2022 Patient ID: 346973 September 29, 2022 Patient ID: 347334 (1st test) Patient ID: 347334 (2nd test) Patient ID: 347334 (3rd test) Patient ID: 347334 (4th test) Patient ID: 347334 (5th test) Patient ID: 347334 (6th test) Patient ID: 347334 (7th test) September 30, 2022 Patient ID: 95112 Patient ID: 347460 Patient ID: 94802 Patient ID: 347504 Patient ID: 95123 October 1, 2022 Patient ID: 347504 (1st test) Patient ID: 347504 (2nd test) Patient ID: 347499 Patient ID: 95367 Patient ID: 347504 (3rd test) Patient ID: 95254 October 2, 2022 Patient ID: 95340 October 13, 2022 Patient ID: 348380 October 15, 2022 Patient ID: 348530 October 16, 2022 Patient ID: 348530 Patient ID: 348537 (1st test) Patient ID: 348537 (2nd test) October 18, 2022 Patient ID: 348687 Patient ID: 348699 October 24, 2022 Patient ID: 349075 October 26, 2022 Patient ID: 349264 (1st test) Patient ID: 349235 Patient ID: 349259 Patient ID: 349265 Patient ID: 349264 (2nd test) Patient ID: 349264 (3rd test) Patient ID: 349276 October 29, 2022 Patient ID: 349420 (1st test) Patient ID: 349420 (2nd test) Patient ID: 349416 Patient ID: 349420 (3rd test) October 30, 2022 Patient ID: 349420 Patient ID: 349502 b) Epoc #3 May 1, 2022 Patient ID: 338369 Patient ID: 338382 Patient ID: 338385 Patient ID: 338394 May 2, 2022 Patient ID: 338481 5. An interview with the laboratory manager on 11/09/2022 at 1430 hours in the laboratory revealed an Individualized Quality Control Plan had not been developed for Epoc #2 or Epoc #3. The laboratory followed the IQCP developed for Epoc #1. This confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) for the BioFire Torch Respiratory 2.1 assay, review of the laboratory's quality control records from June 2022 to August 2022, review of patient test records, and staff

	interview, it was revealed the laboratory failed to have documentation of performing quality control testing when defined by its IQCP. The findings include: 1. A review of the laboratory's Individualized Quality Control Plan for the BioFire Torch Respiratory 2.1 assay revealed the laboratory's modified frequency of quality control testing was defined as: with each new lot with each shipment, and at least every 30 days. 2. A review of the laboratory's quality control records from June 2022 to August 2022 revealed the laboratory performed quality control testing on the following days: June 3, 2022 June 28, 2022 (25 days later) August 13, 2022 (38 days later) 3. A review of patient test records from July 29, 2022 to August 12, 2022 identified the following 8 patients tested on days when the time since the previous quality control testing exceeded the 30 day period as determined by the laboratory's IQCP: a) July 29, 2022 Sample ID: 77506 b) July 30, 2022 Sample ID: 77685 Sample ID: 77823 c) August 6, 2022 Sample ID: 344107 d) August 7, 2022 Sample ID: 80304 e) August 11, 2022 Sample ID: 81823 Sample ID: 81821 Sample ID: 81883 4. An interview with the laboratory manager on 10/08/2022 at 1140 hours in the laboratory - after his review of the records- confirmed the findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's alarm checks from 2021 and 2022, and staff interview, it was revealed the laboratory failed to have documentation of performing 2 of 8 alarm checks as required by its policy. The findings include: 1. A review of the laboratory's policy titled "Blood Bank Temperature Alarm Check" revealed alarm checks were to performed every quarter (3 months). 2. A review of the laboratory's alarm check records from 2021 and 2022 revealed the laboratory failed to have documentation of performing the alarm checks for the 3rd quarter of 2021 and 3rd quarter of 2022. 3. The laboratory was asked to provide documentation of performing the required alarm checks. No documentation was provided. 4. An interview with the laboratory manager on 10/10/2022 at 1530 hours in the laboratory - after his review of the records- confirmed the findings.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures

performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, review of the nursing policies, review of patient transfusion records from August 2022 to November 11, 2022, and staff interview, it was revealed the laboratory failed to have documentation of reviewing transfusion records to ensure potential transfusion reactions were identified. The findings include: 1. A review of the laboratory's policy titled "Blood Administration Policy and Procedure" (approved by the laboratory director on 01/01/2016) revealed: "23. Observe patient for any signs of reaction i.e., urticiaria, itching , hives, chills, fever (report to lab any temperature increase over 2 degrees Fahrenheit.), back pain, change in Blood Pressure +/- 20 mm/hg from baseline, dyspenea, chest tightness, increase in heart rate, flushing, hematuria, or nausea. Observe primarily for circulatory overload, febrile reaction, allergic reaction and hemolytic reaction. If any of these symptoms are noted: a) Stop the transfusion immediately..." 2. A review of patient transfusion records from August 2022 to November 11, 2022 identified 15 of 68 transfusions where the patients' vital signs met the laboratory's criteria for a potential transfusion, however the transfusion was not stopped and a potential transfusion reaction was not investigated. They were: a) Order 6049 Transfusion date: 11/09/2022 Pre-transfusion Blood Pressure: 148/84 1 Hour Blood Pressure: 174/77 Increase: 26 mm/hg 2 Hour Blood Pressure: 180/89 Increase: 32 mm/hg b) Order 6050 Transfusion date: 11/09/2022 Pre-transfusion Blood Pressure: 147/72 30 minute Blood Pressure: 182/73 Increase: 35 mm/hg 1 Hour Blood Pressure: 174/75 Increase: 27 mm/hg 3 Hour Blood Pressure: 171/80 Increase: 24 mm/hg c) Order 2972 Transfusion date: 10/29/2022 Pre-transfusion Blood Pressure: 78/26 15 minute Blood Pressure: 132/36 Increase: 54 mm/hg 30 minute Blood Pressure: 128/34 Increase: 50 mm/hg 1 Hour Blood Pressure: 119/36 Increase: 41 mm/hg d) Order 1663 Transfusion date: 10/24/2022 Pre-transfusion Blood Pressure: 132/100 1 Hour Blood Pressure: 98 /80 Decrease: 34 mm/hg 2 Hour Blood Pressure: 106/58 Decrease: 26 mm/hg 3 Hour Blood Pressure: 88/52 Decrease: 44 mm/hg e) Order 1664 Transfusion date: 10/24 /2022 Pre-transfusion Blood Pressure: 154/88 15 minute Blood Pressure: 117/82 Decrease: 37 mm/hg 30 minute Blood Pressure: 115/60 Decrease: 39 mm/hg 2 Hour Blood Pressure: 133/82 Decrease: 21 mm/hg f) Order 533 Transfusion date: 10/20/22 Pre-transfusion Blood Pressure: 91/57 15 minute Blood Pressure: 120/85 Increase: 29 mm/hg 30 minute Blood Pressure: 130/74 Increase: 39 mm/hg 1 Hour Blood Pressure: 159/99 Increase: 68 mm/hg 2 Hour Blood Pressure: 153/99 Increase: 62 mm/hg g) Order 99483 Transfusion date: 10/17/2022 Pre-transfusion Blood Pressure: 149/54 1 Hour Blood Pressure: 175/65 Increase: 26 mm/hg 2 Hour Blood Pressure: 124/68 Decrease: 25 mm/hg 3 Hour Blood Pressure: 125/72 Decrease: 24 mm/hg h) Order 96637 Transfusion date: 10/07/2022 Pre-transfusion Blood Pressure: 89/58 30 minute Blood Pressure: 117/77 Increase: 28 mm/hg i) Order 91406 Transfusion date: 09/16 /2022 Pre-transfusion Blood Pressure: 90/41 15 minute Blood Pressure: 114/66 Increase: 24 mm/hg 30 minute Blood Pressure: 118/61 Increase: 28 mm/hg 1 Hour Blood Pressure: 118/63 Increase: 28 mm/hg 2 Hour Blood Pressure: 117/60 Increase: 27 mm/hg 3 Hour Blood Pressure: 117/64 Increase: 27 mm/hg j) Order 89582 Transfusion date: 09/09/22 Pre-transfusion Blood Pressure: 115/40 1 Hour Blood Pressure: 85/36 Decrease: 30 mm/hg k) Order 87262 Transfusion date: 08/30/2022 Pre-transfusion Blood Pressure: 111/53 30 minute Blood Pressure: 135/58 Increase: 24 mm/hg 1 Hour Blood Pressure: 144/55 Increase: 33 mm/hg 2 Hour Blood Pressure: 145/55 Increase: 34 mm/hg 3 Hour Blood Pressure: 144/73 Increase: 33 mm/hg l) Order 84101 Transfusion date: 08/19/2022 Pre-transfusion Blood Pressure: 109/63 15 minute Blood Pressure: 136/70 Increase: 27 mm/hg 2 Hour Blood Pressure: 156/79

	Increase: 47 mm/hg 3 Hour Blood Pressure: 155/79 Increase: 46 mm/hg m) Order 84102 Transfusion date: 08/19/2022 Pre-transfusion Blood Pressure: 149/76 3 Hour Blood Pressure: 169/83 Increase: 20 mm/hg n) Order 81139 Transfusion date: 08/09 /2022 Pre-transfusion Blood Pressure: 131/53 30 minute Blood Pressure: 100/49 Decrease: 31 mm/hg 1 Hour Blood Pressure: 103/45 Decrease: 28 mm/hg 2 Hour Blood Pressure: 82/43 Increase: 49 mm/hg o) Order 80527 Transfusion date: 08/08 /2022 Pre-transfusion Blood Pressure: 132/62 2 Hour Blood Pressure: 112/61 Decrease: 20 mm/hg 3. The laboratory was asked to provide documentation the potential transfusion reactions being investigated. No documentation was provided. 4. An interview with the laboratory director on 11/10/2022 at 1445 hours in the manager's office - after his review of the records- confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the quality assurance records, and staff interview, it was revealed the laboratory's quality assurance plan failed to identify and correct problems in analytic. The finding include: 1. The laboratory's quality assurance plan failed to ensure its procedure for patient normal range was followed (refer to D5401). 2. The laboratory's quality assurance plan failed to ensure verification studies were performed (refer to D5421). 3. The laboratory's quality assurance plan failed to ensure calibration verifications were performed (refer to D5439). 4. The laboratory's quality assurance plan failed to ensure quality control values were monitored over time (refer to D5441). 5. The laboratory's quality assurance plan failed to ensure quality control testing was performed each day of patient testing (refer to D5447). 6. The laboratory's quality assurance plan failed to ensure the laboratory's Individualized Quality Control Plan was followed (refer to D5449). 7. The laboratory's quality assurance plan failed to ensure blood bank alarm checks were performed when required (refer to D5555). 8. The laboratory's quality assurance plan failed to ensure the review of transfusion records to detect potential transfusion reactions (D5559).
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of patient test records, and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings include: 1. The laboratory director failed to ensure verification studies were performed (refer to D6013). 2. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). 3. The laboratory director failed to ensure a quality control program was developed and

	followed (refer to D6020). 4. The laboratory director failed to ensure a quality assurance plan identified and corrected problems (refer to D6021). 5. The laboratory director failed to ensure testing personnel had the required training (refer to D6029).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were performed (refer to D5421). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/01-02/2021.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was established and

	maintained. The findings include: 1. The laboratory director failed to ensure quality control results were monitored over time for testing performed on the Alere Epoc Blood Analysis systems (refer to D5441). 2. The laboraory director failed to ensure quality control testing was performed each day of testing on the Alere Epoc Blood Analysis Systems (refer to D5447). 3. The laboratory director failed to ensure the laboratory followed its Individualized Quality Control Plan for Respiratory 2.1 testing on the BioFire Torch system (refer to D5449).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assurance plan identified and corrected problems. The findings include: 1. The laboratory director failed to ensure the laboratory's quality assurance plan identified and corrected problems in pre-analytic systems (refer to D5391). 2. The laboratory director failed to ensure the laboratory's quality assurance plan identified and corrected problems in analytic systems (refer to D5719).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure 7 of 7 testing personnel had documentation of training to perform moderate complexity testing (refer to D6066).
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of patient test records and staff interview, it was revealed the technical consultant failed to provide technical oversight for the laboratory. The findings include: 1. The technical consultant failed to provide technical and scientific oversight (refer to D6036). 2. The technical consultant failed to ensure verification studies were performed (refer to D6040). 3. The technical consultant failed to ensure a quality control program was developed and followed (refer to D6042). 4. The technical consultant failed to identify training needs (refer to D6045). 5. The technical consultant failed to ensure only the technical consultant performed competency assessments(refer to D6046). 6. The technical consultant failed to ensure competency assessments were performed annually (refer to D6054). 7. The technical consultant failed to ensure competency assessments were performed after new instrumentation was installed and prior to testing personnel reporting patient results (refer to D6055).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, review of patient test records, and staff interview, it was revealed the technical consultant failed to provide technical and scientific oversight of the laboratory. The findings include: 1. The technical consultant failed to ensure manufacturer's instructions were followed (refer to D5311). 2. The technical consultant failed to ensure the laboratory's policies were followed (refer to D5401).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure verification studies were performed (refer to D5421).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure a quality control program was established and maintained. The findings include: 1. The technical consultant failed to ensure quality control results were monitored over time for testing performed on the Alere Epoc Blood Analysis systems (refer to D5441). 2. The technical consultant failed to ensure quality control testing was performed each day of testing on the Alere Epoc Blood Analysis Systems (refer to D5447). 3. The technical consultant failed to ensure the laboratory's Individualized Quality Control Plan for Respiratory 2.1 testing on the BioFire Torch system (refer to D5449).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to ensure 7 of 7 testing personnel had documentation of training to perform moderate complexity testing (refer to D6066).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing a competency assessments on 1 of 1 testing personnel. The findings include: 1. A review of the laboratory's personnel records revealed the laboratory manager performed an initial competency assessment on testing personnel number 2 (as listed on Form CMS 209) in April 2022. The laboratory manager was not identified as a technical consultant and did not have the education to qualify as one. 2. An interview with the laboratory manager on 11/07/2022 at 1735 hours in the laboratory revealed he performed the competency assessment and was not aware of the requirement for the technical consultant to perform it. This confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments on 4 of 5 testing personnel. The findings include: 1. A review of the laboratory's personnel records revealed the technical consultant failed to perform the following annual competency assessments: Testing personnel number 3 annual competency assessment due by May 2022 not performed as of November 2022 Testing personnel number 4 annual competency assessment due by February 2022 not performed as of November 2022 Testing personnel number 6 no annual competency assessment in 2021 Testing personnel number 7 no annual competency assessment in 2021 2. The laboratory was asked to provide documentation of the missing competency assessments. No documentation was provided. 3. An interview with the laboratory manager on 11/07/2022 at 1735 hours in the conference room - after his review of the records- confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies for the BioFire Respiratory 2.1 Panel, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on 5 of 5 test personnel prior to reporting patient results when new instrumentation was installed. The findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing testing on the BioFire Torch analyzer using the Respiratory 2.1 panel in November 2021. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing competency assessment prior to performing patient testing 5 of 5 testing personnel. They were (as listed on Form CMS 209): Testing personnel 1 Testing personnel 2 Testing personnel 3 Testing personnel 4 Testing personnel 5 3. The laboratory was asked to provide documentation of assessing the competency of the testing personnel prior to the reporting of patient results. No documentation was provided. 4. An interview with the laboratory manager on 11/08 /2022 at 1100 hours in his office revealed competency assessments were not performed. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 06/01-02/2021
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's test menu, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to have documentation of training for 6 of 7 testing personnel on the BioFire Torch analyzer performing the Respiratory 2.1 panel. The finding include: 1. A review of the laboratory's test menu revealed the laboratory started performing testing on the BioFire Torch analyzer using the Respiratory 2.1 panel in November 2021. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 6 of 7 testing personnel. They were (as listed on Form CMS 209):Testing personnel 1 Testing personnel 2 Testing personnel 3 Testing personnel 5 Testing personnel 6 Testing personnel 7 3. The laboratory was asked to provide documentation of training on 11/07/2022 and 11/08/2022. No documentation was provided. 4. An interview with the laboratory manager on 11/08/2022 at 1100 hours in his office revealed he was unable to locate the training records. This confirmed the findings.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's (API) immunohematology proficiency testing records from 2021 and 2022, and staff interview, it was revealed the laboratory director failed to ensure the review of 2 of 4 proficiency results. The findings include: 1. Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (Immunology /Immunohematology Events 2 and 3) and 2022 (Immunology/Immunohematology Events 1 and 2) revealed the laboratory failed to have documentation of the review of 2 of 4 results. They were: 2021 Immunology/Immunohematology Event 3 2022 Immunology/Immunohematology Event 2 2. The laboratory was asked to provide documentation of the identified proficiency results being reviewed. No documentation was provided. 3. An interview with the laboratory manager on 11/07/2022 at 1535 hours in the conference room - after his review of the records- confirmed the findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient transfusion records from August 2022 to October 2022, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assurance plan identified missing information of transfusion records. The findings include: 1. A review of the laboratory's policy titled "Blood Transfusion and Utilization Review" (approved by the laboratory director on 10/23/2018) revealed: "All units transfused are reviewed for: a. signed doctor's order b. signed consent in medical record c. pre-transfusion criteria d. Two RN signatures before transfusion e. unit started within 30 minutes f.

	unit transfused within 4 hours g. volume give documented h. all charts not meeting criteria are reviewed by the pathologist i. all data collected is summarized and presented to the pathologist for review monthly. 2. A review of patient transfusion records from August 2022 to October 2022 identified the following records which were not documented as required on the forms: a) signed doctor's orders (2 of 68 records) Patient ID 348095 Transfusion date: 10/09/2022 Patient ID: 346767 Transfusion date: 09/20/2022 b) unit transfused within 4 hours (1 of 68 records) Patient ID: 346579 Transfusion date: 09/18/2022 Unit issued: 1621 hours Transfusion ended: 2135 hours Elapsed time: 5 hours 14 minutes 3. An interview with the laboratory director on 11/10/2022 at 1445 hours in the manager's office - after his review of the records- confirmed the findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure 1 of 7 testing personnel had documentation of education to qualify to perform high complexity testing (refer to D6171).
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 7 testing personnel who performed high complexity testing (refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation to qualify 1 of 7 testing personnel who performed high complexity testing. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 7 testing personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed that testing personnel number 6 (as listed on Form CMS 209) had documentation of a

	Bachelor of Science diploma, however, the diploma did not identify what field it was in. There were no transcripts available for review to determine if testing personnel qualified to perform high complexity testing. 3. The laboratory was asked to provide addition documentation to qualify testing personnel number 2. No documentation was provided. 4. An interview with the laboratory manager on 11/07/2022 at 1535 hours in the conference room - after his review of the records- confirmed the findings.